



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

[Signature]

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,910	01/22/2001	Mark Hochman	3486-023 DIV2	2509
22440	7590	06/30/2004	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC			THANH, LOAN H	
270 MADISON AVENUE			ART UNIT	PAPER NUMBER
8TH FLOOR			3763	
NEW YORK, NY 100160601			DATE MAILED: 06/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,910	HOCHMAN ET AL.	
	Examiner	Art Unit	
	LoAn H. Thanh	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04/23/04.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-9 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 18-19 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 17, 2-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The claim rejections under 35 USC 112 , 2nd paragraph have been obviated in view of the amendment filed 12/03/03.

Applicant has not responded to the IDS and as such has not been considered.

The request for inventorship correction has not been approved in view of the amendment to the claims filed 12/03/03. The claims being directed to the device are similar to the patent.

Inventorship

The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted.

The statement of facts by an inventor or inventors to be added or deleted does not explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

A 37 CFR 3.73(b) submission has not been received to support action by the assignee.

It lacks the written consent of any assignee of one of the originally named inventors.

Information Disclosure Statement

The information disclosure statement filed 5/7/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because MU 7502580-9 has not been

Art Unit: 3763

translated. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following informalities:

Reference numeral "58 " has been designated as both slot and top surface". See page 8, line 11 and page 9, line 2.

Reference numeral "95A" and "96" has been designated as both finger pad. See page 8, line 32 and page 9, line 1-2.

Applicant is requested to update the status of the application which priority is claimed.

Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "source of therapeutic" is not supported for in the

specification. Applicant is suggested to amend the specification to include this reference if originally claimed or replace with 'cartridge" which is supported.

Claim Objections

Claim 17 is objected to because of the following informalities: The "source of therapeutic " in line 4 should be replaced with " cartridge". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9,17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "said pump" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "said container" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,4,10 rejected under 35 U.S.C. 102(e) as being anticipated by

Rondelet et al. (U.S. Patent No. 5,25,967).

Rondelet et al. teach an injection system having a container/syringe, a pump, and a controller/computer which operates the pump and is adapted to move the plunger. With respect to claim 10, a selector is inherent in that it is the on and off switch such as power button. With respect to the functional language, it is the Examiner's position that the claims are directed to a device claim and as such there are no structurally distinguishing features which would differentiate the claims from the prior art of record.

Further, the device is capable of functioning as claimed.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinello (U.S. Patent No. 5,180,371).

Spinello disclose an injection system comprising a container/syringe, a pump, a controller/ microcontroller, a piston for injecting or aspirating , and a selector/switch which operates in different modes. See columns 3, 5-6,7 and 10. See figures 5-8. With respect to the functional language, it is the Examiner's position that the claims are directed to a device claim and as such there are no structurally distinguishing features

which would differentiate the claims from the prior art of record. Further, the device is capable of functioning as claimed.

Response to Arguments

Applicant's arguments filed 12/29/03 have been fully considered but they are not persuasive. Applicant's arguments are more narrow than claimed. Applicant has not claimed that "commands are used to automatically advance the piston to an empty position and then withdrawn it to a full position to fill the reservoir." Further, it is unclear how the reservoir/syringe can be filled if the source/cartridge is within the reservoir. The rejection has been maintained in view of the Examiner's best understanding of applicant's claimed language in view of the disclosure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H.Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT